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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/670,922

09/24/2003

Theodore K. Kyle

C75105C1

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08/10/2007

GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220

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EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,922

Applicant(s)

KYLE ET AL.

Examiner

Kendra D. Carter

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of May 4, 2007 made to the office action filed January 3, 2007. Claims 29-44 are pending. Claim 29 is amended and claims 37-44 are new.

In light of the amendments, the 35 USC 112, first paragraph, is withdrawn.

In light of the terminal disclaimer filed May 4, 2007, the nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,660,754 B1, is withdrawn.

The Applicant's arguments of the 35 USC 103(a) rejection of claims 29-36 as being unpatentable over Cooper et al. (US 5,055,478) were found not persuasive, and thus upheld.

The Examiner has addressed the Applicant's arguments below.

Due to the amendment to the claims and the addition of new claims, the modified 35 USC 103(a) rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. (US 5,055,478).

Cooper et al. teaches a method for eliminating an individual's tobacco smoking habit by gradually decreasing tobacco consumption over a first period of time until no further tobacco is consumed. An alternative oral nicotine source is then progressively administered as a substitute for tobacco consumed during sequential consumption periods over each succeeding day for approximately two weeks until no further tobacco is consumed. Following a period during which the administration of the alternative nicotine source is maintained it, too, is progressively eliminated over a period of approximately sixteen weeks (see the abstract in its entirety; addresses claims 29 and 37). During the first time period, the method includes the additional step of administering an alternative nicotine source (see column 2, lines 52-57). Since the tobacco consumption is only decreased gradually, there is less trauma for the individual.

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As such, the anxiety to which the individual is subjected, as well as the irritability that is experienced remains at a minimum (see column 2, lines 66-68 to column 3 lines 1-2). The overall method provides a far more effective means for eliminating an individual's tobacco smoking habit (i.e. improving an individual's rate or success in the cessation of tobacco usage; see column 3, lines 10-12; addresses claim 37). The nicotine source is administered orally in the form of chewing gum or through mucous membranes or external exposed body tissues such as an suppository, snuff, transdermal patch, lozenge, sucker or the like (see column 3, lines 14-15 and 20-24; addresses claims 33, 34, 41 and 42). One Nicorette gum, which includes 2 mg of nicotine is administered to the individual and slowly chewed throughout the first consumption period (see column 6, line 39-43; addresses claims 35, 36, 43 and 44). Progressive alternative nicotine administration occurs at a rate of one additional consumption period per day over a time period of approximately 14-16 days until no further tobacco is consumed (see column 3, lines 43-47; addresses claims 29 and 37). The individual is conditioned to receiving a steady dose of nicotine throughout the day rather than sudden nicotine spikes or peaks from smoking. Advantageously, it is easing to address and reverse nicotine addiction from this steady level by simply retraining the individual over time to accept progressively less each day (see column 3, lines 56-62). The initial step in this decrease is eliminating the administration of the alternative nicotine source only during the first consumption period each day for the period of one week. Each day is broken down into consumption periods of one hour each (see column 4, lines 23-24). The administration is then progressively eliminated during sequential consumption periods

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over each succeeding week until no further alternative nicotine source is consumed (see column 4, lines 1-7; addresses claims 29 and 37). At the end of this time the nicotine dependency of the individual is overcome and the individual's tobacco smoking habit has been successfully eliminated (see column 4, lines 10-12; addresses claims 29 and 37). Alternatively, the tobacco consumption can be replaced by combining the step to abruptly stop tobacco consumption and administering an alternative nicotine source at the first maintenance level (see column 4, lines 25-29).

To address the specific administration of one unit of an alternative nicotine source after waking or each consecutive one hour time unit after waking, waiting one hour, and then continuing an individual's normal tobacco usage pattern, Cooper et al. teaches that (1) each day is broken down into consumption periods of one hour each (see column 4, lines 23-24); (2) one Nicorette gum, is administered to the individual and slowly chewed throughout the first consumption period (see column 6, line 39-43); and (3) at first the patient is allowed to consume the normal administration of any other nicotine source after consuming the Nicorette gum (see column 6, lines 45-46). Thus, the first consumption (i.e. after waking) is the alternative nicotine source (i.e. Nicorette gum), then after one hour the patient consumes the normal consumption of nicotine.

Cooper et al. does not specifically teach administering one unit of an alternative nicotine source every one to two hours for substantially five weeks, two to four hours for

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substantially three weeks, or four to eight hours for substantially three weeks in length (see claims 29 i-iv, 30-32, 37 i-iv, and 38-40).

To one of ordinary skill in the art would have found it obvious to combine the method of Cooper et al. with administering one unit of an alternative nicotine source every one to two hours for substantially five weeks; two to four hours for substantially three weeks, or four to eight hours for substantially three weeks in length because Cooper et al. teaches that (1) each day is broken down into consumption periods of one hour each (see column 4, lines 23-24); and (2) following a period during which the administration of the alternative nicotine source is maintained it, too, is progressively eliminated over a period of approximately sixteen weeks (see the abstract in its entirety). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (“[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art.” See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

The motivation to combine the method of Cooper et al. with administering one unit of an alternative nicotine source every one to two hours for substantially five weeks;

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two to four hours for substantially three weeks, or four to eight hours for substantially three weeks in length because Cooper et al. teaches a gradual process of eliminating tobacco and nicotine such that there is less trauma for the individual. As such, the anxiety to which the individual is subjected, as well as the irritability that is experienced remains at a minimum (see column 2, lines 66-68 to column 3 lines 1-2). In addition, a prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974).

Response to Arguments

35 USC 103(a)

Applicant's arguments filed May 4, 2007 have been fully considered but they are not persuasive.

The Applicant argues that the obviousness to combine the method of Cooper with the steps taught by the present invention involves hindsight reasoning which is impermissible when determining obviousness. Optimization of the Cooper regime does not render each and every element of the claimed invention. Cooper progressively eliminates nicotine derived from an alternative nicotine source by eliminating the administration of the alternative nicotine source from sequential consumption periods each progressive week until no further alternative

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nicotine source is consumed. This regimen may be very difficult to adhere to for an individual still nicotine dependent and facing nicotine cravings and may more easily fall into relapse. In contrast, the method of the instant invention allows the individual to continue to consume the alternative nicotine source periodically throughout the entire day, but with reduced frequency. Thus Cooper does not render obvious the present invention.

The Examiner disagrees because Cooper teaches the Applicant's method steps of 29 a-d and 37 a-d, but not specifically i-iv or either 29 or 37. Obviousness and motivation is taught by Cooper et al. for 29 and 37 i-iv because Cooper teaches a gradual process of eliminating tobacco and the alternative nicotine such that there is less trauma for the individual. As such, the anxiety to which the individual is subjected, as well as the irritability that is experienced remains at a minimum (see column 2, lines 66-68 to column 3 lines 1-2). Thus, optimizing the method of Cooper such that the gradual process of the alternative nicotine source is administered alternatively every one to two, two to four, or four to eight hours versus eliminating the alternative nicotine source sequentially every hour each week is obvious because both are gradual processes of reducing the individual's nicotine usage over time and improving an individual's rate of success in the cessation of tobacco usage. It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d

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380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose

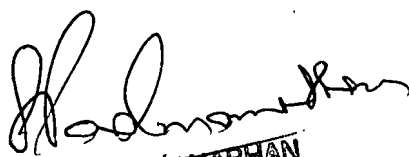
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telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER